



HIV and Viral Hepatitis Policy Watch

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The *Policy Watch* provides timely updates and resources on Hill and Administration activities impacting HIV and viral hepatitis programs. Please go to NASTAD's website at www.NASTAD.org for more information.

SPECIAL ISSUE - AIDS DRUG ASSISTANCE PROGRAMS (ADAPs): LAY OF THE LAND

The AIDS Drug Assistance Program (ADAP) plays a key role in the federal and state response to the U.S. domestic HIV/AIDS epidemic by providing life-saving medications to uninsured or underinsured individuals who are living with HIV. In this period of extended economic downturn, ADAPs are at the center of a perfect storm as more individuals without insurance rely on safety net programs for care and more people are being diagnosed due to expanded HIV testing. These and other factors have caused tremendous growth among ADAPs nationwide, with ADAP client enrollment and client utilization reaching their highest levels in FY2010 since the inception of the program.

There have been a myriad of attempts to shore-up support for ADAPs, including President Obama's announcement on World AIDS Day of \$35 million in new money for the program, with the goal of removing over 3,000 individuals from ADAP waiting lists. While NASTAD and HIV/AIDS community advocates laud these efforts, the true need for ADAPs is approximately \$360 million in FY2012. This would permit all ADAPs to provide medications to new enrollees, maintain current benefits and mend the structural deficits that have grown in recent years due to a less than adequate level of funding. NASTAD continues to engage in finding solutions to this ongoing crisis by working in tandem with the Obama Administration, Congress, state ADAP programs, industry and other community partners. This Policy Watch provides an overview of the current issues facing ADAPs.

Current Status of ADAP

Federal funding has not kept pace with the growth in the number of [ADAP clients served](#). According to NASTAD's [2011 National ADAP Monitoring Project Annual Report](#), from June 2007 to June 2010, the total number of ADAP clients served increased by 33 percent, while federal funding increased only 6 percent. As a result, many ADAPs have instituted cost-containment measures or are considering implementing new or additional cost-containment measures and wait-lists in the upcoming grant year.

As of December 15, 2011, there are 4,333 individuals on ADAP waiting lists in 12 states. Since the release of final FY2011 Ryan White grant awards in September 2011, including \$40 million in ADAP emergency relief funding for states with waiting lists or other cost-containment measures in place, some ADAPs have been able to reduce the overall number of individuals on their waiting list. However, as states remove individuals from their waiting lists, they are adding new individuals to their program. The demand for ADAP has not dwindled and ADAP waiting lists will begin to plateau and then grow again in the coming months. It is unknown how the additional \$35 million announced by President Obama on World AIDS Day will be allocated to states. This may

also have an impact on reducing the number of individuals on ADAP waiting lists.

Funding of ADAP and Shared Responsibility: Three-Pronged Strategy

In order to meet the needs of nearly 191,000 individuals living with HIV receiving ADAP services and tens of thousands more who will turn to the program throughout the next year to meet their HIV medication needs, ADAPs, state and federal governments and industry partners must all work together to solve the ADAP crisis.

Federal funding

The federal share of the national ADAP budget has been declining as a share of the overall ADAP budget from a high of 68 percent in 2000 to the current share of 45 percent. NASTAD has continuously advocated for increased federal resources to keep up with the increase in ADAP utilization.

As previously mentioned, President Obama recently [announced](#) \$35 million in new resources for ADAPs from the Prevention and Public Health Fund. The Health Resources and Services Administration (HRSA) is currently developing the distribution formula and mechanism for this emergency funding. NASTAD provided HRSA with recommended principles for distributing this funding. These principles are: (1) some funding should be directed to all ADAPs to meet continued growth needs, while the remainder should be targeted to states with the highest unmet needs; (2) ADAPs should be allowed to apply for the targeted funding and become eligible by demonstrating the need for the additional resources (rather than a predetermined set of eligible ADAPs); (3) the distribution of funding should occur through existing ADAP funding "pots;" (4) ADAPs should have one year from the date of receipt to obligate the funds; (5) ADAPs should be permitted to expend this funding in any way that contributes to increased access to medications; and (6) any ADAPs who do not apply for the funding this year should remain eligible for future funding. An announcement from HRSA regarding distribution of the \$35 million in additional funds is expected within the next several weeks.

NASTAD has also worked with other HIV/AIDS community partners to advocate for an increase for ADAPs in the FY2012 Labor, Health and Human Services, Education, and Related Agencies Appropriation. Though the true need is significantly higher, NASTAD and community partners are advocating for at least a \$55 million increase for ADAPs commensurate with the President's recommended increase in his budget request.

Later today, Congress will vote on a [proposed spending bill](#) for the final FY2012 appropriations that includes a \$15 million increase for ADAPs. Congress is expected to pass this legislation, which will fund HIV/AIDS program through the rest of FY2012.

State funding

Many ADAPs have strong state-federal partnerships. State revenues for ADAPs have increased significantly since the inception of the program to help meet program demands. In FY2010, states contributed \$346 million, or approximately 19 percent, of the overall ADAP budget. State contributions have increased by \$52 million (18 percent) from 2007 to 2010. Many local and state coalitions are advocating for state legislatures to increase their current levels of funding in order to sustain current services and help to eliminate access restrictions for eligible clients.

Pharmaceutical manufacturers

The ADAP Crisis Task Force (ACTF), convened by NASTAD, negotiates with manufacturers for reduced drug prices on behalf of all ADAPs. The ACTF has agreements with 12 manufacturers that produced an estimated savings for ADAPs of \$259 million in FY2009 with a cumulative savings of over \$1.2 billion since 2003. Given the gravity of the ADAP crisis, the ACTF recently met with all eight antiretroviral manufacturers to discuss solutions for eliminating waiting lists, providing medications to new clients and maintaining formularies. In addition to existing agreements, the ACTF recently announced additional enhanced, voluntary discounts, rebates and price freezes

with [Boehringer Ingelheim Pharmaceuticals](#), [Gilead Sciences](#) and [Janssen Therapeutics](#). Additional enhanced agreements are expected to be finalized next week and the ACTF will continue to negotiate enhanced agreements with the remaining companies. These agreements expire at the end of December 2013, when the health care landscape will change dramatically due to implementation of the Affordable Care Act.

Welvista

For over 18 years Welvista, a nonprofit organization located in Columbia, South Carolina, has been providing access to prescription medications to the uninsured and underserved throughout South Carolina. Welvista partners with 16 branded pharmaceutical companies who donate medications and a network of over 3,500 health care providers making them one of the largest mail-order pharmacies for the uninsured in the nation. In 2010, the Heinz Family Philanthropies, Abbott Laboratories, and Welvista collaborated to expedite access to HIV medications for individuals currently waiting for access to ADAPs across the nation. This initiative was developed to find a solution to a call for help from NASTAD to find ways to simplify access to medications for individuals on ADAP waiting lists rather than the standard patient assistance program (PAP) processes that currently exist. The initiative is funded through the Heinz Family Philanthropies and Abbott Laboratories, Bristol-Myers Squibb, Boehringer Ingelheim, Gilead Sciences, Janssen Therapeutics, Merck and Company and ViiV Healthcare.

On December 1, 2011, the MAC AIDS Fund [announced](#) a new partnership with Welvista that will provide Welvista with \$500,000 for increased patient outreach, education and expansion of patient assistance programs to meet the medication needs of an expanded number of people living with HIV/AIDS.

Clinton Proposal

Former President Bill Clinton [announced](#) during his remarks on World AIDS Day that the U.S. should consider providing generic drugs to people on ADAP waiting lists for the next two years (until health reform is implemented and the economy improves). The announcement leaves many unanswered questions about the extent and logistics of using generic drugs to address the ADAP wait list issue. NASTAD will continue to monitor developments regarding this proposal and educate key stakeholders about the challenges associated with implementing such a proposal for ADAPs.

ADAPs and Viral Hepatitis

It is estimated that up to 30 percent of people living with HIV are also infected with the hepatitis C virus (HCV) and up to 15 percent with the hepatitis B virus (HBV). Co-infection increases the progression to liver disease and can occur without symptoms. A number of ADAPs provide vaccination, treatment and/or diagnostics for viral hepatitis. According to a [NASTAD ADAP Monitoring Report](#), 25 ADAPs covered HBV treatments and 22 ADAPs covered HCV treatment in 2010. HCV is classified as an HIV-related opportunistic infection, due to the relatively high co-infection rate of HIV and HCV. Because there is no national funding source specifically for HCV treatment, most of the burden for treating co-infected patients has fallen on ADAPs and Ryan White programs. Additionally, 22 ADAPs covered hepatitis A (HAV) and HBV vaccines for people living with HIV and 7 ADAPs provided diagnostics for HCV.

ADAPs and Health Reform

As the Affordable Care Act (ACA) is implemented, there are many opportunities ADAPs can explore that increase access to care for people living with HIV/AIDS.

In an effort to help uninsured individuals obtain coverage prior to 2014, the ACA includes provisions that established a Pre-existing Condition Insurance Plan (PCIP) in each state in July 2010. In some states, ADAPs have enrolled clients in PCIPs and thereby, rather than purchasing drugs for the clients, provide wrap around services (paying for premiums, deductibles and co-pays) on their behalf. Each state has its own procedures and requirements as to who can enroll in

the program and some states have limits as to the number of "slots" available for certain programs, including HIV-positive individuals. Therefore, not all states have been able to take advantage of this provision. NASTAD continues to work closely with states to enable them to take advantage of this ACA provision which expires on December 31, 2013 when the full expansion of Medicaid and health exchanges will occur.

In addition, CMS released an updated [guidance](#) on Section 1115 waivers for state Medicaid programs that allow states the option to cover eligible pre-disabled adults living with HIV. Without the waiver in place, eligible individuals must have a disability in order to qualify for Medicaid. The 1115 waiver option may be of particular interest to states as a way to address ADAP waiting lists, alleviate ADAP funding shortfalls and leverage federal matching funds for HIV/AIDS care and treatment. States have significant flexibility in the design of the waivers under the guidance and application template issued by CMS in June 2011. NASTAD is partnering with the [Treatment Action Expansion Project \(TAEP\)](#) to provide technical assistance (TA) to states regarding applying for the 1115 waiver.

Other issues that ADAPs will face throughout the implementation of ACA, both before and after 2014, include integration with health insurance exchanges, the Medicaid expansion of coverage and the calculation of client income to reflect changes in the ACA.

NASTAD's Response

NASTAD is preparing ADAPs for full implementation of health reform and will continue to develop new TA tools and activities to assist with transitional and emerging issues. In 2011, NASTAD conducted two regional meetings, funded by the MAC AIDS Fund, for all ADAPs to begin preparing for implementation of health reform. NASTAD will convene additional meetings in 2012 on this topic. In addition, NASTAD convened a [plenary session](#) during the 2011 National ADAP TA Meeting that provided an update on ADAP funding and advocacy issues and a snap-shot of the basics of health reform and a [plenary session](#) that updated ADAPs on the implementation of PCIPs.

In 2012, NASTAD will continue to provide TA to ADAPs in preparation for implementation of the ACA. Additionally, NASTAD will develop and release fact sheets, interactive tools and an education webinar series to help ADAPs bridge the gap until 2014.

History of ADAPs

A timeline of major events in the history of ADAPs can be found [here](#).

Upcoming Events

Ryan White Part B Application due - January 17, 2012

Beginning of the ADAP Fiscal Year - April 1, 2012

NASTAD Regional Technical Assistance Meetings (tentatively scheduled for June and August 2012)

NASTAD National ADAP TA Meeting - August 22-24, 2012, Washington, DC



National Alliance of State and Territorial AIDS Directors
444 North Capitol Street, NW • Suite 339 • Washington D.C. 20001 • ph: (202)
434-8090
www.NASTAD.org • em: nastad@nastad.org